

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENCY: Office of the Assistant Secretary for Health, Office of Population Affairs

FUNDING OPPORTUNITY TITLE: Announcement of Availability of Funds for Title X

Family Planning- Research Grants - Innovations in Family Planning Clinical Service

Delivery and Studies to Address Opportunities and Barriers for Linking Family Planning

Services and Substance Use Disorder Screening and Treatment

ACTION: Notice

ANNOUNCEMENT TYPE: INITIAL COMPETITIVE GRANT

FUNDING OPPORTUNITY NUMBER: PA-FPR-19-001

CFDA NUMBER: 93.974

CFDA PROGRAM: Family Planning Service Delivery Improvement Research Grants

DATES:

Technical Assistance:

A technical assistance webinar for potential applicants will be held within 4 weeks from the posting of the announcement. Please visit www.hhs.gov/opa for more information.

We recommend you review the entire announcement promptly so you can have any questions answered well in advance of the application due date. We also recommend you subscribe to this announcement in Grants.gov so you receive any amendments, question and answer documents, or other updates.

Applications: Your application is due June 14, 2019 by 6 p.m. Eastern Time. To receive consideration, you must submit your application electronically via Grants.gov no later than this due date and time. If you do not submit your application by the specified deadline, we will return it to you unread. You must submit electronically via Grants.gov unless you obtain a written exemption from this requirement 2 business days in advance of the deadline from the Director, HHS/Office of the Assistant Secretary for Health (OASH) Office of Grants Management (OGM). To obtain an exemption, you must request one via email from the HHS/OASH OGM, and provide details as to why you are technologically unable to submit electronically through Grants.gov. Your request should be submitted at least 4 business days prior to the application deadline to ensure your request can be considered prior to 2 business days in advance of the deadline. If you request an exemption, include the following in your e-mail request: the HHS/OASH announcement number; your organization's DUNS number; your organization's name, address and telephone number; the name and telephone number of your Authorizing Official; the Grants.gov Tracking Number (for example, GRANT####) assigned to your submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to ogm.oash@hhs.gov. Note: failure to have an active System for Account Management (SAM) registration prior to the application due date will not be grounds for receiving an exemption to the electronic submission requirement. Failure to follow Grants.gov instructions to ensure software compatibility will not be grounds for receiving an exemption to the electronic submission requirement.

The HHS/OASH OGM will only accept applications via alternate methods (hardcopy paper via U.S. mail or other provider or PDF via email) from applicants obtaining prior written approval. If you receive an exemption, you must still submit your application by the deadline. Only applications submitted through the Grants.gov portal or

alternate format (hardcopy paper via U.S. mail or other service or PDF via email) with an approved written exemption will be accepted. *See* Section D.7 (“Other Submission Requirements”) for information on application submission mechanisms.

To ensure adequate time to submit your application successfully, HHS/OASH recommends that you register as early as possible in Grants.gov since the registration process can take up to one month. You must register an authorizing official for your organization. HHS/OASH does not determine your organization’s authorizing official; your organization makes that designation. For information on registering for Grants.gov, refer to <http://www.grants.gov> or contact the Grants.gov Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or support@grants.gov.

Your organization is strongly encouraged to register multiple authorized organization representatives in Grants.gov to ensure someone is available to submit your application.

EXECUTIVE SUMMARY: The Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health (OASH) announces the availability of funds for Fiscal Year (FY) 2019 grant awards under the authority of Title X of the Public Health Service Act (42 U.S.C. 300 *et seq.*). Title X of the Public Health Service Act authorizes programs related to family planning. Section 1004 of the Act, as amended, authorizes the Secretary of Health and Human Services to award grants to entities for research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population. Regulations pertaining to grants for research projects are set out at 42 CFR part 52.

This notice solicits applications for projects to conduct research on 1) innovative family planning clinical service delivery models and 2) clinical interventions for linking family planning services and substance use disorder screening and treatment. OPA seeks applications from public and private nonprofit entities for up to 10 grants with a ceiling of up to \$800,000 each in order to conduct research to improve the delivery of family planning services offered under Title X of the Public Health Service Act.

HHS/OASH encourages applicants to review all program requirements, eligibility information, application format and submission information, evaluation criteria, and other information in this funding announcement to ensure that its application complies with all requirements and instructions.

A. PROGRAM DESCRIPTION:

This Funding Opportunity Announcement (FOA), issued by the Office of Population Affairs (OPA), invites applications from public or private nonprofit entities to conduct research that will lead to feasible and effective strategies to increase access to quality Title X family planning services among hard to reach populations or provide family planning services in resource limited areas, as well as among individuals who misuse opioids and/or other substances, including those with substance use disorders (SUDs).

Applicants should address only ONE priority area per application, but an entity may submit multiple applications. If an applicant submits more than one application for the same focus area, then only the last application submitted for that focus area will be considered.

Priority areas for these research grants are as follows:

- 1) Innovative family planning clinical service delivery models that can be used to increase access to quality Title X family planning services among hard to reach populations or provide Title X family planning services in resource limited areas.
- 2) Meeting the family planning needs of women and men who misuse opioids and/or other substances, including those with substance use disorders (SUDs), so they can prevent or achieve pregnancy when desired.

Applicants must clearly identify in the project narrative which focus area the proposal addresses.

BACKGROUND

The U.S. Department of Health and Human Services, Office of Population Affairs (OPA) seeks to assist all Americans in achieving their desired number and spacing of children by providing family planning and related preventive health education, counseling, and medical services.

Section 1004 of the Public Health Service Act authorizes the Secretary to “make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.” The section authorizes funding for projects to conduct data analysis and related research and evaluation on issues of interest to the family planning field, as well as research into specific priority areas related to service delivery improvement for Title X family planning services and clinics. This FOA solicits applications for research that will lead to feasible and effective activities to increase the ability of individuals and couples to achieve their desired family planning goals. The information will help family planning centers across the U.S. improve their family planning service delivery.

PRIORITY AREAS:

1) Innovative family planning clinical service delivery models.

Family planning services have typically been provided in clinical settings. However, clinics are not always easily accessible to clients in need of publicly funded family planning services. In rural areas, the nearest clinic may be too far away to access, especially without reliable transportation. Clients may also have other barriers to accessing clinics, such as limited clinic hours, availability of certain providers, long waiting times, and competing demands^{16,17}. The goal of this priority area is to identify innovative family planning clinical service delivery models that could be used to provide quality family planning services outside of the traditional clinic setting. It is important that these models comply with requirements of the Title X statute, any legislative mandates, and any program regulations applicable to Title X service delivery, as of the time the requirement is applicable and in effect. Copies of the Title X statute, regulations, and legislative mandates may be downloaded from the Office of Population Affairs web site at <https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/statutes-and-regulations/index.html>.

Research projects addressing this focus area may conduct one or more of the following types of studies:

- Evaluations of innovative family planning clinical service delivery models currently being used that reach hard to reach populations or provide family planning services in resource limited areas.
- Pilot studies of innovative clinical service delivery models providing family planning services to hard to reach populations and/or providing family planning services in resource limited areas.

Innovative ideas are encouraged, but research leading to feasible, wide-scale, effective interventions is of primary importance.

- 2) Meeting the family planning needs of women and men who misuse opioids and/or other substances, including those with substance use disorders (SUDs).

The long-term, overarching goal of OPA is to improve reproductive health outcomes for women and men, including adolescents, by reducing unplanned pregnancies, improving birth spacing, and improving maternal and infant health. Increasing access to family planning services for women and men who misuse opioids and other substances is critical to achieve the long-term goal of OPA as this population experiences a high level of unmet family planning needs.¹ Women with opioid and other substance use disorders have low rates of most or moderately effective contraceptive method use and high rates of unintended pregnancy and induced terminations,^{2,3} and are at higher risk of delivering a newborn with adverse health outcomes.^{4,5} Meeting the family planning needs of these individuals can help them achieve their reproductive health goals and lead to improved maternal and infant health in the United States.

Substance use disorders have become epidemic in the United States, with drug overdoses accounting for 52,404 U.S. deaths in 2015, including 33,091 (63.1%) deaths that involved use of an opioid.⁶ Between 1999 and 2015, the rate of deaths from prescription opioid overdoses increased 471 percent among women, compared to an increase of 218 percent among men, with heroin deaths among women increasing at double the rate of men.⁷

Reproductive age women with opioid use disorders are of particular concern because of the potential risks posed to the developing fetus, such as neonatal abstinence syndrome (NAS), a drug withdrawal syndrome in newborns following birth. The incidence of NAS in the United

States has increased nearly five-fold during 2000 to 2012, from 1.2 to 5.8 per 1,000 hospital births.^{8,9} In 2012, approximately 22,000 newborns were diagnosed with NAS, which translates to 1 birth every 25 minutes,⁸ with total annual hospital and provider costs now exceeding \$316 million.¹⁰ Further, parts of the United States experience higher rates of NAS than others, with incidence of NAS as high as 33 per 1,000 hospital births in states such as West Virginia.¹¹

Although a substantial percentage of pregnant women are exposed to opioids during pregnancy, all sexually active women of reproductive age using opioids are at risk of having an opioid-exposed fetus because half of all pregnancies in the United States are unintended at the time of conception.^{12,13} Approximately 14% of pregnant women are dispensed an opioid at some point during pregnancy¹³ and 5% of pregnant women report using nonmedical opioids in the past year,¹⁴ but one third of reproductive age women (ages 15-44) in the United States had at least one opioid prescription dispensed by outpatient pharmacies in the past year.¹⁵

This priority area focuses on filling a critical gap in knowledge regarding family planning service provision, i.e., how to increase access to family planning services for women and men who misuse opioids and/or other substances, including those with substance use disorders (SUDs).

Research projects addressing this priority area may conduct one or more of the following types of studies:

- Evaluation of clinical interventions designed to increase the availability of services that aid in the identification, intervention, referral and treatment of individuals with opioid and other substance use disorders in family planning clinics.

- Clinical pilot studies of interventions designed to increase the availability of services that aid in the identification, intervention, referral and treatment of individuals with opioid and other substance use disorders in family planning clinics.
- Evaluation of current clinical interventions designed to increase linkage between family planning services and substance use treatment for men and women of child-bearing age with opioid and other substance use disorders.
- Clinical pilot studies of interventions designed to increase linkage between family planning services and substance use treatment for men and women of child-bearing age with opioid and other substance use disorders.

Innovative ideas are encouraged, but research leading to feasible, wide-scale, effective interventions is of primary importance and interest.

AUTHORITY: Section 1004 of the Public Health Service Act (42 U.S.C. § 300a-2)

B. FEDERAL AWARD INFORMATION

The Office of Population Affairs intends to make funds available for competing grants.

We will fund awards in annual increments (budget periods) and generally for a project period up to three (3) years, although we may approve shorter project periods. Budget periods may also vary from the estimate indicated below due to timing of award issuance or other administrative factors. Funding for all approved budget periods beyond the first is generally level with the initial award amount and is contingent upon the availability of funds, satisfactory progress of the project, adequate stewardship of Federal funds, and the best interests of the Government.

Award Information

Estimated Federal Funds Available: \$4,000,000

Anticipated Number of Awards: 10

Award Ceiling (Federal Funds including indirect costs): \$800,000 per budget period

Award Floor (Federal Funds including indirect costs): \$200,000

Anticipated Start Date: 09/16/2019

Estimated Period of Performance: Not to exceed 3 years

Anticipated Initial Budget Period Length: 12 months

Type of Award: Grant

Type of Application Accepted: Electronic via Grants.gov **ONLY unless an exemption is granted**

C. ELIGIBILITY INFORMATION

1. Eligible Applicants.

Any public or private nonprofit entity located in any one of the 50 United States, the District of Columbia, Commonwealth of Puerto Rico, U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, and the Republic of the Marshall Islands is eligible to apply for a grant under this announcement. Faith-based organizations and American Indian/Alaskan Native/Native American (AI/AN/NA) organizations are eligible to apply.

2. Cost Sharing or Matching

You are not required to provide cost sharing or matching in your proposed budget.

3. Other Eligibility Information

Application Responsiveness Criteria

We will review your application to determine whether it meets the following responsiveness criteria. If your application does not meet the responsiveness criteria, we will disqualify it from the competition; we will not review it beyond the initial screening.

The applicant appears to have demonstrated:

- A clear relationship to only one of the FOA research priority areas by specifically stating in the Abstract Summary form (see Section D: APPLICATION AND SUBMISSION INFORMATION) which priority area is to be addressed.

Application Disqualification Criteria

If you successfully submit an application, we will screen it to ensure it meets the below requirements. If we determine your application fails to meet the criteria described below we will disqualify it, that is, we will **not** review it and will give it **no** further consideration.

- a) You must submit your application electronically via www.grants.gov (unless an exemption was granted 2 business days prior to the deadline) by the date and time indicated in the DATES section of this announcement.
- b) If you successfully submit multiple applications from the same organization for the same project, we will only review the last application received by the deadline.
- c) HHS/OASH/OGM must deem your application eligible according to section C.1 *Eligible Applicants*.
- d) You must complete the required forms in the application package: SF-424, SF-424A, SF-424B, SF-LLL, and Project Abstract Summary.

- e) Your Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ ” x 11” inch page size, with 1” margins on all sides (top, bottom, left and right) and font size not less than 12 points.
- f) Your Project Narrative must **not** exceed 40 pages. NOTE: The following items do not count toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-424B, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables).
- g) Your total application, including the Project Narrative plus Appendices, must **not** exceed 80 pages. NOTE: items listed in “e” immediately above do not count toward total page limit.
- h) Your Federal funds request including indirect costs must **not** exceed the maximum indicated in Award Ceiling.
- i) Your Federal funds request including indirect costs must **not** be below the minimum indicated in Award Floor.
- j) Your application must meet the **Application Responsiveness Criteria** outlined above.

D. APPLICATION AND SUBMISSION INFORMATION

1. Address to Request Application Package

You may obtain an application package electronically by accessing Grants.gov at <http://www.grants.gov/>. You can find it by searching the CFDA number shown on page 1 of this funding opportunity announcement. If you have problems accessing the application or difficulty downloading, contact:

Office of Grants Management

Phone: 240-453-8822

Email: ogm.oash@hhs.gov

2. Content and Form of Application Submission

i. Application Format

Your application must be prepared using the forms and information provided in the online application package.

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Disqualification Criteria listed in Section C. The page limit does not include the Budget Narrative (including budget tables), required forms, assurances, and certifications as described in the Application Disqualification Criteria. Please do not number pages or include a table of contents. Our grants management system will generate page numbers once your application is complete. If your application exceeds the specified page limits for the Project Narrative or Project Narrative plus Appendices when printed on 8.5” X 11” paper by HHS/OASH/OGM, we will not review it. We recommend you print out your application before submitting electronically to ensure that it is within the page limits and is easy to read.

You must double-space the Project Narrative pages.

You should use an easily readable typeface, such as Times New Roman or Arial. You *must* use 12-point font. You may single-space tables or use alternate fonts but you must ensure the tables are easy to read.

Appendices Format

Your Appendices should include any specific documents outlined in Section D.2.iii., under the heading “Appendices” in the Application Content section of this funding opportunity announcement. Your documents should be easy to read. You should use the same formatting specified for the Project Narrative. However, documents such as résumés/CVs, organizational

charts, tables, or letters of commitment may use formatting common to those documents, but the pages must be easy to read. All of your appendices must be uploaded as a single, consolidated file in the Attachments section of your Grants.gov application.

Project Abstract Summary Format

You must complete the Project Abstract Summary form provided in the application package. The abstract will be used to provide reviewers with an overview of the application and will form the basis for the application summary in grants management and program summary documents. If your project is funded, HHS may publish information from your form; therefore, do not include sensitive or proprietary information. Research awards may enter zero for “Estimated number of people to be served as a result of the award of this grant.”

Budget Narrative Format

The Budget Narrative should use the formatting required of the Project Narrative for the explanatory text. Budget tables may be single-spaced but should be laid out in an easily-readable format and within the printable margins of the page.

ii. Application Content

Successful applications will contain the following information:

Project Narrative Content

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether your project meets the minimum requirements for an award under this announcement. The Project Narrative should provide a clear and concise

description of your project. HHS/OASH recommends that your project narrative include the following components:

Problem Statement

Goals and Objectives

Proposed Methodology

Special Populations Served

Outcomes

Project Management

Evaluation

Dissemination

Organizational Capability

Problem Statement. You should describe in this section, in both quantitative and qualitative terms, the nature and scope of the specific and particular problem or issue, and the proposed intervention it is designed to address. You should detail how the project will potentially affect the populations served, specific subgroups within those populations, and other interested stakeholders as identified. We recommend that you focus your problem statement on the specific aspects of the history, existing literature, current status, and policy considerations bearing on the priority area, and the roles of the national, state, and local agencies responsible for their operation, rather than providing a broad or sweeping historical overview that is not directly related to the research activities.

Goals and Objectives. You should describe in this section your project's proposed goal(s) and major objectives. Unless your project involves multiple, complex interventions, we recommend you have only one overall goal.

Proposed Methodology. You should provide a clear and concise description of the methodology you are proposing to use to address the need identified in the program announcement and the problem described in the "Problem Statement" above. You should explain the rationale for using a particular methodology and to present a clear connection between identified gaps and needs and your proposed activities. Your proposal should detail the nature of the activities to be undertaken, how they address system gaps and identified issues, and how they will assist in achieving the overall project goals and objectives. You should clarify why these specific activities were selected (i.e., has this approach been successful in other settings? How does the research suggest this direction?). Also note any major barriers you anticipate encountering and how your project will be able to overcome those barriers. At a minimum, you should:

- Indicate why the chosen methodology is appropriate to answer the research questions of interest to OPA.
- Provide detailed descriptions of the specific methodology to be used.
- Show power calculations, if appropriate, for key project outcomes to assure the study is adequately powered to detect differences between comparison groups or provide sufficiently precise prevalence or incidence estimates.
- Note any major barriers you anticipate encountering and how your project will be able to overcome those barriers.

- Indicate a plan for addressing the problems or issues. Provide detailed descriptions of specific products or outcomes proposed for development or modification.
- If subrecipients will be used, describe the role and makeup of potential subrecipients intended to be involved in completing specific tasks, and identify the level of effort each subrecipient is anticipated to provide in completing programmatic activities.
- Provide specifics about the activities, expected outcomes, and barriers for all anticipated years of the award.

Special Populations Served. You should describe how your proposed study will serve hard to reach populations and resource limited areas.

Outcomes. You should clearly identify the measurable outcome(s) that will result from your project. HHS/OASH will not fund any project that does not include measurable outcomes. In addition to discussion in the narrative, you should describe how you envision the project will benefit the field at large.

A “measurable outcome” is an observable end-result that describes how the proposed research contributes to the general knowledge base of the priority areas. It demonstrates the “impact” of the activity. For example, a change in a client’s financial, health, and/or functional status; mental well-being; knowledge; skill; attitude; awareness; or behavior. It can also describe a change in the degree to which participants exercise choice over the

types of services they receive, or whether they are satisfied with the way a service is delivered. Additional examples include: a change in the responsiveness or cost-effectiveness of a service delivery system; a new model of support or care that can be replicated; new knowledge; a measurable increase in community awareness; or a measurable increase in persons receiving services. A measurable outcome is not a measurable output, such as: the number of clients served; the number of training sessions held; or the number of service units provided.

You should keep the focus of this section on describing *what* outcome(s) will be produced by the project. In many cases, it is very appropriate for a project to have only *ONE* outcome that it is trying to achieve through the research activity reflected in the project's design.

Project Management. You should clearly delineate the roles and responsibilities of project staff and subrecipients and how they will contribute to achieving the project's objectives and outcomes. You should specify who will have day-to-day responsibility for key tasks such as: leadership of project; monitoring the project's on-going progress; preparation of reports; and communications with other partners and HHS/OASH. You should also describe the approach that will be used to monitor and track progress on the project's tasks and objectives. You should clearly identify the individual who will serve as the Principal Investigator/Project Director and that individual's qualifications. HHS/OASH expects that, throughout the award period, the Principal Investigator/Project Director will have involvement in, and substantial knowledge about, all aspects of the project.

Evaluation. You should describe the methods you will use to evaluate whether or not the proposed activities achieve their measurable outcome(s) and assess and evaluate the impact of activities you propose. You should describe *how* you will measure and report on the outcomes of the project. You should describe the quantitative and qualitative tools and techniques that you will employ to measure the outcome(s) and how you will identify and document the “lessons learned.”

Dissemination. You should describe the method you will use to disseminate the project’s results and findings in a timely manner and in easily understandable formats to the population served, the general public, and other parties who might be interested in using the results of the project. HHS/OASH may publish (including on a website), all appropriate findings and products. Therefore, you should propose other, innovative approaches to informing parties who might be interested in using the results of your project to inform practice, service delivery, program development, and/or policy-making, especially to those parties who would be interested in replicating the project. HHS/OASH expects that nationwide dissemination of products and knowledge will occur.

Projects awarded funding will be expected to dedicate a portion of their time and project resources to the following activities and products:

- Disseminate research findings through publications and/or presentations at family planning, substance use disorder or public health research meetings.
- Participate in potential annual meetings with other OPA research grantees and OPA staff to discuss research approaches, methodologies, and findings.

- Federal grant support must be acknowledged in any publication developed using Title X funds (see Section F FEDERAL AWARD ADMINISTRATION INFORMATION, Acknowledgement of Funding and HHS Rights to Materials and Data).
- Specific plans for each expected product should be explained in detail in the proposal.

Organizational Capability. You should describe your organization's capability to successfully implement the proposed project. You should describe how your agency (or the particular division of a larger agency which will have responsibility for this project) is organized, the nature and scope of its work, and the capabilities it possesses. Your description should cover capabilities of the applicant agency not included elsewhere in the program narrative, such as any current or previous relevant experience and/or the record of the project team in preparing cogent and useful reports, publications, and other products. If appropriate, include an organizational chart in your Appendices showing the relationship of the project to the current organization.

Also include information about any contractual and/or supportive staff/organization(s) that will have a secondary role(s) in implementing the project and achieving project goals.

Budget Narrative Content

You must complete the required budget forms and submit a budget narrative with detailed justification as part of your application. You must enter the project budget on the Budget Information Non-construction Programs standard form (SF 424A) according to the directions

provided with this standard form. The budget narrative consists of a detailed line-item budget that includes calculations for all costs and activities by “object class categories” identified on the SF-424A and justification of the costs. You must indicate the method you are selecting for your indirect cost rate. See Indirect Costs below for further information.

Project budget calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient to verify the calculations. If matching or cost sharing is required, you must include a detailed listing of any funding sources identified in box 18 of the SF-424 (Application for Federal Assistance).

Please be sure to carefully review section D.6 Funding Restrictions for specific information regarding allowable, unallowable, and restricted costs.

You must provide an object class category budget using Section B, box 6 of the SF 424A for the first year of the proposed project. Provide a budget justification, which includes explanatory text and line-item detail, for the first year of the proposed project. The budget narrative should describe how the categorical costs are derived. Discuss the necessity, reasonableness, and allocation of the proposed costs.

For subsequent budget years, provide a summary narrative and line item budget. For categories or items that differ significantly from the first budget year, provide a detailed justification explaining these changes. Note, **do not** include costs beyond the first budget year in the object class budget in box 6 of the SF- 424A or box 18 of the SF-424; the amounts entered in these sections should only reflect the first budget year.

Your budget narrative should justify the overall cost of the project as well as the proposed cost per activity, service delivered, and/or product. For example, the budget narrative

should define the amount of work you have planned and expect to perform, what it will cost, and an explanation of how the result is cost effective. For example, if you are proposing to provide services to clients, you should describe how many clients are you expecting to serve, the unit cost of serving each client, and how this is cost effective.

Use the following guidelines for preparing the detailed object class budget required by box 6 of the SF-424A. The object class budget organizes your proposed costs into a set of defined categories outlined below. Both federal and non-federal resources (when required) must be detailed and justified in the budget narrative. “Federal resources” refers only to the HHS/OASH funds for which you are applying. “Non-federal resources” are all other non-HHS/OASH federal and non-federal resources. We recommend you present budget amounts and computations in a columnar format: first column, object class categories; second column, federal funds requested; third column, non-federal resources; and last column, total budget.

Sample Budget Table

Object Class	Federal Funds Requested	Non-federal Resources	Total Budget
Personnel	\$100,000	\$25,000	\$125,000

Note, subrecipient/contract and consultant detailed costs should all be included in those specific line items, not in the overall project object class line items, i.e., subrecipient travel should be included in the Contractual line item not in Travel.

Object Class Descriptions and Required Justifications

Personnel Description: Costs of staff salaries and wages, excluding benefits.

Personnel Justification: Clearly identify the project director or principal investigator, if known at the time of application. Provide a separate table for personnel costs detailing for each proposed staff person: the title; full name (if known at time of application), time commitment to the project as a percentage or full-time equivalent; annual salary and/or annual wage rate; federally funded award salary; non-federal award salary, if applicable; and total salary. No salary rate may exceed the statutory limitation in effect at the time you submit your application (see D.6 Funding Restrictions, *Salary Rate Limitation* for details). Do not include the costs of consultants, personnel costs of delegate agencies, or of specific project(s) and/or businesses to be financed by the applicant. Contractors and consultants should not be placed under this category.

Sample Personnel Table

Position Title and Full Name	Percent Time	Annual Salary	Federally-funded Salary	Non-federal Salary	Total Project Salary
Project Director, John K. Doe	50%	\$100,000	\$50,000	\$0	\$50,000
Data Assistant, Susan R. Smith	10%	\$30,000		\$3,000	\$3,000

Fringe Benefits Description: Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

Fringe Benefits Justification: Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, Federal Insurance Contributions Act (FICA) taxes, retirement insurance, and taxes.

Travel Description: Costs of travel by staff of the applicant organization only.

Travel Justification: For each trip proposed for applicant organization staff only, show the date of the proposed travel, total number of traveler(s); travel destination; duration of trip; per diem; mileage allowances, if privately owned vehicles will be used; and other transportation costs and subsistence allowances. **Do not** include travel costs for subrecipients or contractors.

Equipment Description: “Equipment” means an article of nonexpendable, tangible personal property having a useful life of more than one year per unit and an acquisition cost that equals or exceeds the lesser of: (a) the capitalization level established by the organization for the financial statement purposes, or (b) \$5,000. (Note: Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation, shall be included in or excluded from acquisition cost in accordance with your organization's regular written accounting practices.)

Equipment Justification: For each type of equipment requested you must provide a description of the equipment; the cost per unit; the number of units; the total cost; and a plan for use of the equipment in the project; as well as a plan for the use, and/or disposal of, the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy, or section of its policy, that includes the equipment definition; include this with your Budget Narrative file. Reference the policy in this justification and include the policy copy in your Budget Narrative file (not your appendices).

Supplies Description: Costs of all tangible personal property other than those included under the Equipment category. This includes office and other consumable supplies with a per-unit cost of less than \$5,000.

Supplies Justification: Specify general categories of supplies and their costs. Show computations and provide other information that supports the amount requested.

Contractual Description: Costs of all contracts or subawards for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc. Include third-party evaluation contracts, if applicable, and contracts or subawards with subrecipient organizations (with budget detail), including delegate agencies and specific project(s) and/or businesses to be financed by the applicant. This line item is not for individual consultants.

Contractual Justification: Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open, and free competition. Recipients and subrecipients are required to use 45 CFR § 75.329 procedures and must justify any anticipated procurement action that is expected to be awarded without competition and exceeds the simplified acquisition threshold fixed by 41 U.S.C. § 134, as described in 2 CFR § 200.88, and currently set at \$250,000. Recipients may be required to make pre-award review and procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc., available to HHS/OASH.

Note: Whenever you intend to delegate part of the project to another agency, the applicant must provide a detailed budget and budget narrative for each subrecipient/contractor, by agency title, along with the same supporting information referred to in these instructions. If you plan to select the subrecipients/contractors post-award and a detailed budget is not available

at the time of application, the applicant must provide information on the nature of the work to be delegated, the estimated costs, and the process for selecting the delegate agency.

Other Description: Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to: consultants; insurance; professional services (including audit charges); space and equipment rent; printing and publication; training, such as tuition and stipends; participant support costs including incentives, staff development costs; and any other costs not addressed elsewhere in the budget.

Other Justification: Provide computations, a narrative description, and a justification for each cost under this category.

Indirect Costs Description: Total amount of indirect costs. This category has one of two methods that an applicant may select. You may only select one.

1) Your organization currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant federal agency. You should enclose a copy of the current approved rate agreement in your Budget Narrative file. If you request a rate that is less than allowed, your authorized representative must submit a signed acknowledgement that the organization is accepting a lower rate than allowed.

2) Per 45 CFR § 75.414(f) Indirect (F&A) costs, “any non-Federal entity [i.e., applicant] that has never received a negotiated indirect cost rate, ... may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. As described in § 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards

until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time.”

This method only applies if you have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. If you are waiting for approval of an indirect cost rate, you may request the 10% de minimis. If you choose this method, costs included in the indirect cost pool must not be charged as direct costs to the award.

Indirect Costs Justification: Provide the calculation for your indirect costs total, i.e., show each line item included in the base, the total of these lines, and the application of the indirect rate. If you have multiple approved rates, indicate which rate as described in your approved agreement is being applied and why that rate is being used. For example, if you have both on-campus and off-campus rates, identify which is being used and why.

Program Income Description: Program income means gross income earned by your organization that is directly generated by this project if funded except as provided in 45 CFR § 75.307(f). Program income includes but is not limited to income from fees for services performed or the use or rental of real or personal property acquired under the award. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also 45 CFR §§ 75.307, 75.407 and 35 U.S.C. §§ 200-212 (applies to inventions made under Federal awards).

Program Income Justification: Describe and estimate the sources and amounts of Program Income that this project may generate if funded. Unless being used for cost sharing, if

applicable, these funds should not be added to your budget. This amount should be reflected in box 7 of the SF-424A.

Non-Federal Resources Description: Amounts of non-federal resources that will be used to support the project as identified in box 18 of the SF-424. For all federal awards, any shared costs or matching funds and all contributions, including cash and third-party in-kind contributions, must be accepted as part of the recipient's cost sharing or matching when such contributions meet all of the criteria listed in 45 CFR § 75.306. For awards that require matching by statute, you will be held accountable for projected commitments of non-federal resources in your application budgets and budget justifications by budget period or by project period for fully-funded awards, even if the justification by budget period, or by project period for fully-funded awards, exceeds the amount required. Your failure to provide the required matching amount may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports. For awards that do not require matching or cost sharing by statute or regulation, where "cost sharing" refers to costs of a project in addition to Federal funds requested that you voluntarily propose in your budget, if your application is successful, we will include this non-federal cost sharing in the approved project budget and you will be held accountable for the non-federal cost-sharing funds as shown in the Notice of Award (NOA). Your failure to provide voluntary cost sharing of non-federal resources that have been accepted by HHS/OASH as part of the approved project costs and that are shown as part of the approved project budget in the NOA may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports. Note, you will not receive any preference, priority, or special consideration in the funding process for voluntarily including non-Federal cost sharing in your proposed budget.

Non-federal Resources Justification: You must provide detailed budget information for every funding source identified in box 18. “Estimated Funding (\$)” on the SF-424. Provide this documentation as part of your Budget Narrative file, not your Appendices.

You must fully identify and document in your application the specific costs or contributions you propose in order to meet a matching requirement. You must provide documentation in your application on the sources of funding or contribution(s). In-kind contributions must be accompanied by a justification of how the stated valuation was determined. Matching or cost sharing must be documented by budget period (or by project period for fully-funded awards).

If your application does not include the required supporting documentation, it will not be disqualified from competitive review; however, it may impact your score under the evaluation criteria in Section E.1 of this announcement.

Plan for Oversight of Federal Award Funds

You must include a plan for oversight of federal award funds which describes:

- how your organization will provide oversight of federal funds and how award activities and partner(s) will adhere to applicable federal award and programmatic regulations. Include identification of risks specific to your project as proposed and how your oversight plan addresses these risks.
- the organizational systems that demonstrate effective control over and accountability for federal funds and program income, compare outlays with budget amounts, and provide accounting records supported by source documentation.

- for any program incentives proposed, the specific internal controls that will be used to ensure only qualified participants will receive them and how they will be tracked.
- organizational controls that will ensure timely and accurate submission of Federal Financial Reports to the OASH Office of Grants Management and Payment Management Services as well as timely and appropriate withdrawal of cash from the Payment Management System.

Appendices

All items described in this section will count toward the total page limit of your application. You must submit them as a single electronic file uploaded to the Attachments section of your Grants.gov application.

References for project and/or budget narratives

Your references should include citation information for all the source literature cited in the project and/or budget narratives.

Work Plan.

Your Work Plan should reflect, and be consistent with, the Project Narrative and Budget Narrative, and must cover all years of the project period. However, each year's activities should be fully attainable in one budget year. You may propose multi-year activities, as well as activities that build upon each other, but each phase of the project must be discreet and attainable within a single budget year. Your Work Plan should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks, action steps, or products that will be pursued or developed to achieve the goal and outcome(s). For each major task of each year, action step, or product, your work plan should identify the timeframes involved (including start- and end-dates), and the lead person responsible for completing the task.

Letters of Commitment from Subrecipient Organizations and Agencies

You should include signed Letters of Commitment for all organizations and entities that have been specifically named as a subrecipient to carry out any aspect of the project. The signed letters of commitment ***must detail*** the specific role and resources that will be provided, or activities that will be undertaken, in support of the applicant. The organization's expertise, experience, and access to the targeted population(s) should also be described in the letter of commitment. Letters of commitment are not the same as letters of support. Letters of support are letters that are general in nature that speak to the writer's belief in the capability of an applicant to accomplish a goal/task. Letters of support also may indicate an intent or interest to work together in the future, but they lack specificity. You should NOT provide letters of support, and letters of support such as this will not be considered during the review.

Curricula Vitae/Résumés for Key Project Personnel

You must submit with your application curricula vitae and/or résumés of the Project Director/Principal Investigator and all other Key Personnel. Key Personnel includes those individuals who will oversee the technical, professional, managerial, and support functions and/or assume responsibility for assuring the validity and quality of your organization's program. This includes at a minimum Program Manager/Program Coordinator. We encourage individuals to use their full name (first, middle, last) on these documents to distinguish them for verification in the System for Award Management exclusion records.

Organizational Chart

You must submit with your application an organizational chart. This chart should show the structure of the applicant organization and the relationships and relative ranks of the key staff involved in the project.

3. Unique Entity Identifier and System for Award Management (SAM)

- You are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal awards through Grants.gov. It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is *free and easy* to obtain.
- You will find instructions on the Grants.Gov web site as part of the organization registration process at <http://www.grants.gov/web/grants/applicants/organization-registration.html>.
- Your organization must register online in the System for Award Management (SAM). **Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations.**
- If you are registering a new entity or renewing your registration, you must submit a notarized letter formally appointing an Entity Administrator to [SAM.GOV](http://www.sam.gov) For detailed instructions on the content of the letter and process for domestic entities see: https://www.fsd.gov/fsd-gov/answer.do?sysparm_kbid=d2e67885db0d5f00b3257d321f96194b&sysparm_search=kb0013183
- A quick start guide for registrants is available at https://www.sam.gov/sam/transcript/Quick_Guide_for_Grants_Registrations.pdf. You should allow a *minimum* of five days to complete an initial SAM registration. Allow up to 10 business days *after you submit* your registration for it to be active in SAM. This timeframe may be longer if SAM flags the information you

provide for manual validation. You will receive an email alerting you when your registration is active.

- If your organization is already registered in SAM, you must renew your SAM registration *each* year. Organizations registered to apply for Federal awards through <http://www.grants.gov> will need to *renew* their registration in SAM.
- You should make sure your SAM registration information is accurate, especially your organization's legal name and physical address including your ZIP+4. Should you successfully compete and receive an award, this information must be included on a Notice of Award. For instructions on updating this information see https://gsafsd.service-now.com/fsd-gov/answer.do?sysparm_kbid=c3d982af6fb8d5006f348d412e3ee47e
- It may take 24 hours or more for SAM updates to take effect in Grants.gov, so if you plan to apply for this funding opportunity or think you might apply, you should ***ensure your organization's registration is active in SAM well before the application deadline and will be active through the competitive review period.***
- If you are successful and receive an award, you must maintain an active SAM registration with current information at all times during which your organization has an active award or an application or plan under consideration by an HHS agency.

HHS/OASH cannot make an award until you have complied with these requirements. In accordance with 2 CFR § 25.205, at the time an award is ready to be made, if you have not complied with these requirements, HHS/OASH:

- May determine that you are not qualified to receive an award; and

- May use that determination as a basis for making an award to another applicant.

Should you successfully compete and receive an award, all first-tier sub-award recipients must have a DUNS number at the time you, the recipient, make a sub-award.

4. Submission Dates and Times

You must submit your application for this funding opportunity by **the date and time indicated in the DATES section of this announcement**. Your submission time will be determined by the date and time stamp provided by Grants.gov when you **complete** your submission.

If you fail to submit your application by the due date and time, we will not review it, and it will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with <http://www.grants.gov>. Grants.gov can take up to 48 hours to notify you of a successful or rejected submission. You are better off having a less-than-perfect application successfully submitted and under consideration than no application.

If your submission fails due to a system problem with Grants.gov, we may consider your application if you provide verification from Grants.gov indicating system problems existed at the time of your submission **and that time was before the submission deadline**. A “system problem” does not include known issues for which Grants.gov has posted instructions regarding how to successfully submit an application such as compatible Adobe versions or file naming

conventions. **As the applicant, it is your responsibility to review all instructions available on Grants.gov regarding successfully submitting an application.**

5. Intergovernmental Review

This program is not subject to the Intergovernmental Review requirements of Executive Order 12372, “Intergovernmental Review of Federal Programs,” as implemented by 45 CFR part 100.

6. Funding Restrictions

Direct and Indirect Costs proposed and, if successful, charged to the HHS/OASH award must meet the cost requirements of 45 CFR part 75 “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards,” Subpart E—Cost Principles. These requirements apply to you, the applicant, and any subrecipients. You should thoroughly review these regulations before developing your proposed budget.

Indirect costs may be included per 45 CFR § 75.414. See the Budget Narrative section of this announcement for more information. To obtain a negotiated indirect cost rate with the Federal Government you may contact the U.S. Department of Health and Human Services Cost Allocation Services (CAS) regional office that is applicable to your State. CAS regional contact information is available at <https://rates.psc.gov/fms/dca/map1.html>.

Pre-Award Costs:

Pre-award costs are not allowed.

Salary Rate Limitation:

Each year’s appropriations act limits the salary rate that we may award and you may charge to HHS/OASH grants and cooperative agreements. You should not budget award funds to pay the salary of an individual at a rate in excess of Federal Executive Pay Scale Executive

Level II. As of January 7, 2018, the Executive Level II salary is \$189,600. This amount reflects an individual's base salary exclusive of fringe benefits and any income that an individual working on the award project may be permitted to earn outside of the duties to the applicant organization. This salary rate limitation also applies to subawards/subcontracts under an HHS/OASH award.

An example of the application of this limitation for an individual devoting 50% of their time to this award is broken down below:

Individual's <i>actual</i> base full time salary: \$350,000	
50% of time devoted to project, i.e. .5 FTE	
Direct salary (\$350,000 x .5)	\$175,000
Fringe (25% of salary)	\$43,750
Total	\$218,750
Amount that may be claimed on the application budget due to the legislative salary rate limitation:	
Individual's base full time salary <i>adjusted</i> to Executive Level II: \$189,600 with 50% of time devoted to the project	
Direct salary (\$189,600 x .5)	\$94,800
Fringe (25% of salary)	\$23,700
Total amount allowed	\$118,500

Appropriate salary rate limits will apply as required by law.

7. Other Submission Requirements

Electronic Submission

HHS/OASH requires that all applications be submitted electronically via the Grants.gov portal unless an exemption has been granted. If you submit an application via any other means of electronic communication, including facsimile or electronic mail, it *will not* be accepted for review unless you receive an exemption as described in the DATES section of this announcement.

You may access the Grants.gov website portal at <http://www.grants.gov>.

Applications, excluding required standard forms, must be submitted as three (3) files (see acceptable file types below). One file must contain the entire Project Narrative, another the entire Budget Narrative including supporting documentation described in the Budget Narrative content section; and the third file must contain all documents in the Appendices. Any additional files submitted as part of the Grants.gov application will not be accepted for processing and will be excluded from the application during the review process.

Any files uploaded or attached to the Grants.gov application must be Adobe PDF, Microsoft Word, or image formats (JPG, GIF, TIFF, or BMP only) and must contain a valid file format extension in the filename. HHS/OASH strongly recommends that electronic applications be uploaded as Adobe PDF. If you convert to PDF prior to submission you may prevent any unintentional formatting that might occur with submission of an editable document. Please note, even though Grants.gov allows you to attach any file format as part of your application, HHS/OASH restricts this practice and only accepts the file formats identified above. Any file submitted as part of the Grants.gov application that is not in a file format listed above will not be accepted for processing and will be excluded from the application during the review process.

Any file submitted as part of the Grants.gov application that contains password protection will not be accepted for processing and will be excluded from the application during the review

process. We will not contact you for passwords or resubmission of unprotected files.

Unprotected information in the application will be forwarded for consideration but password protected portions will not. You should avoid submitting personally identifiable information such as personal contact information on résumés.

In addition, the use of compressed file formats such as ZIP, RAR, or Adobe Portfolio will not be accepted. We will not contact you for resubmission of uncompressed versions of files. Compressed information in the application will not be forwarded for consideration.

You must submit your application in a format that can easily be copied and read by reviewers. We do not recommend that you submit scanned copies through Grants.gov unless you confirm the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a single sheet to avoid exceeding the page limitation. If you submit documents that do not conform to these instructions, we will exclude them from your application during the review process.

Important Grants.gov Information

You may access the electronic application for this program on <http://www.grants.gov>. You must search the downloadable application page by the Funding Opportunity Number or CFDA number, both of which can be found on page 1 of this funding opportunity announcement.

To ensure successful submission of your application, you should carefully follow the step-by-step instructions provided at <http://www.grants.gov/web/grants/applicants/apply-for-grants.html>. These instructions are kept up-to-date and also provide links to Frequently Asked Questions and other troubleshooting information. **You are responsible for reviewing all Grants.gov submission requirements on the Grants.gov site.**

You should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through Grants.gov. See Contacts below. See Section D.3 for requirements related to DUNS numbers and SAM registration.

Non-profit Status

If you are a non-profit organization, you must submit documentation of nonprofit status as part of your application. Any of the following constitutes acceptable proof of such status:

- a) A reference to the Applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS code;
- b) A copy of a currently valid IRS tax exemption certificate;
- c) A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals; or
- d) A certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status.

E. APPLICATION REVIEW INFORMATION

1. Criteria: Federal staff and an independent review panel will assess all eligible applications according to the following criteria. Disqualified applications will not be reviewed against these criteria.

The award decision will take into account the extent to which the organization's proposal represents a comprehensive plan for developing research on one of the two priority areas. The table below provides the review criteria and points assigned to each criterion, as well as the suggested section of the narrative where the criteria should be addressed.

Review Criteria and Points	Suggested Narrative Section where criteria should be addressed
<p>Address Priority Area</p> <p>a. The extent to which the proposal addresses one of the OPA priority areas listed in this FOA.</p> <p>(8 points)</p>	<ul style="list-style-type: none"> • Problem Statement
<p>Appropriate Study Goals and Objectives</p> <p>a. The extent to which the proposal addresses the significance of the project.</p> <p>b. The extent to which the goals and objectives are clearly described and address the problem described in the Problem Statement.</p> <p>c. The consistency between the Goals and Objectives in the Project Narrative and the goals, objectives, accomplishments and tasks included in the work plan.</p> <p>(15 points)</p>	<ul style="list-style-type: none"> • Goals and Objectives

Review Criteria and Points	Suggested Narrative Section where criteria should be addressed
<p>Study Plan</p> <ol style="list-style-type: none"> The extent to which the proposal describes the scientific merit of the project. The extent to which the proposal presents a coherent and well-justified research plan for the 3- year project period. Inclusion of a description of the special population served by the project activities, e.g., men and women of child-bearing age with opioid and other substance use disorders or hard to reach populations and resource limited areas The feasibility of the project and the likelihood of its producing meaningful results within the proposed project period. Inclusion of power calculations, if applicable to the project. <p>(20 points)</p>	<ul style="list-style-type: none"> Proposed Activity
<p>Measurable and Appropriate Outcomes</p> <ol style="list-style-type: none"> The extent to which the outcomes are measurable and appropriately address the goals and objectives of the project. <p>(20 points)</p>	<ul style="list-style-type: none"> Outcome
<p>Strong Project Management</p> <ol style="list-style-type: none"> The extent to which the organization proposes a clear project management plan to accomplish stated goals and objectives. The competency of the proposed staff in relation to the type of research involved. <p>(10 points)</p>	<ul style="list-style-type: none"> Project Management

Review Criteria and Points	Suggested Narrative Section where criteria should be addressed
Dissemination Capability a. The extent to which the applicant organization demonstrates in the application its ability to disseminate the results to the public, in the timeframes specified in the Project Narrative recommendations (above). (10 points)	<ul style="list-style-type: none"> • Dissemination
Follow-through on Project a. The extent to which the organization demonstrates having the ability to complete the study proposed. (7 points)	<ul style="list-style-type: none"> • Organizational Capability
Appropriate Budget a. Reasonableness of proposed budget in relation to the proposed project, the amount of grant funds necessary for completion of the project and adequacy of resources already available for the project. (10 points)	<ul style="list-style-type: none"> • Budget Narrative

2. Review and Selection Process

Each HHS/OASH Program's office is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth above.

An independent review panel will evaluate applications that meet the responsiveness criteria, if applicable, and are not disqualified. These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies. Based on the Application Review Criteria as outlined under Section E.1, the reviewers will comment on and score the applications, focusing their comments and scoring decisions on the identified criteria. In addition to the independent review panel, Federal staff will review each application for programmatic, budgetary, and grants management compliance.

The Deputy Assistant Secretary for Population Affairs will provide recommendations for funding to the Grants Management Officer to conduct risk analysis. In providing these recommendations, the Deputy Assistant Secretary for Population Affairs will take into consideration the following additional factor(s):

- Distribution of awards among the two focus areas; and,
- Geographic distribution of award recipients.

3. Review of Risk Posed by Applicant

The HHS/OASH will evaluate, in accordance with 45 CFR § 75.205, each application recommended for funding by the program official indicated in Review and Selection Process for risks before issuing an award. This evaluation may incorporate results of the evaluation of eligibility or the quality of an application. If we determine that a Federal award will be made, special conditions that correspond to the degree of risk assessed will be applied to the Federal award. Such conditions may include additional programmatic or financial reporting or releasing funds on a reimbursable rather than cash advance basis. OASH will use a risk-based approach and may consider any items such as the following:

- (a) Your financial stability;
- (b) Quality of management systems and ability to meet the management standards prescribed in 45 CFR part 75;
- (c) History of performance. Your record in managing Federal awards, if you are a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if

applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(d) Reports and findings from audits performed; and

(e) Your ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

Prior to making a Federal award with a total Federal share greater than the simplified acquisition threshold (currently \$150,000), we are required to review and consider any information about you that is in the designated integrity and performance system accessible through the System for Award Management (SAM) (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). You may, at your option, review information in SAM and comment on any information about yourself that a Federal awarding agency previously entered and is currently available through SAM. We will consider any comments by you, in addition to the other information in the designated system, in making a judgment about your integrity, business ethics, and record of performance under Federal awards when completing the review of risk.

If an we do not make an award to you because we determine your organization does not meet either or both of the minimum qualification standards as described in 45 CFR §75.205(a)(2), we must report that determination to FAPIIS, if certain conditions apply. At a minimum, the information in the system if you are a prior Federal award recipient must “demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics.” 45 CFR § 75.205(a)(2); see also 45 CFR §75.212 for additional information.

4. Final Award Decisions, Anticipated Announcement, and Federal Award Dates

Upon completion of risk analysis and concurrence of the Grants Management Officer, HHS/OASH will issue Notices of Award. No award decision is final until a Notice of Award is issued. All award decisions, including level of funding if an award is made, are final and you may not appeal.

HHS/OASH seeks to award funds as much in advance of the anticipated project start date shown in Section B “Federal Award Information,” as practicable, with a goal of 10-15 days. Note this is an estimated start date and award announcements may be made at a later date and with a later project period start date.

F. FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal Award Notices

HHS/ OASH does not release information about individual applications during the review process. If you would like to track your application, please see instructions at <http://www.grants.gov/web/grants/applicants/track-my-application.html>. The official document notifying you that a project application has been approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer of the HHS/OASH OGM. If you are successful, you will receive this document via system notification from our grants management system (Grant Solutions) and/or via e-mail. This document notifies the successful recipient of the amount awarded, the purposes of the award, the anticipated length of the project period, terms and conditions of the award, and the amount of funding to be contributed by the recipient to project costs, if applicable.

If you receive an NOA, we strongly encourage you to read the entire document to ensure your organization’s information is correct and that you understand all terms and conditions. You

should pay specific attention to the terms and conditions, as some may require a time-limited response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the award for assistance and monitoring.

If you are unsuccessful or deemed ineligible according to the disqualification criteria, you will be notified by HHS/OASH by email and/or letter. If your application was reviewed by the independent review panel, you may receive summary comments pertaining to the application resulting from the review process. On occasion, you may receive a letter indicating that an application was approved but unfunded. These applications may be kept active for one year and may be considered for award without re-competing should funds become available during the hold period.

2. Administrative and National Policy Requirements

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, or other Department regulations and policies in effect at the time of the award.

In addition, your organization must comply with all terms and conditions outlined in the Notice of Award, the U.S. Department of Health and Human Services (HHS) Grants Policy Statement (GPS), requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts. The current HHS GPS is available at <http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf> Please note HHS plans to revise the HHS GPS to reflect changes to the regulations; 45 CFR parts 74 and 92 have been superseded by 45 CFR part 75.

You may only use award funds to support activities outlined in the approved project plan. If your application is funded, your organization will be responsible for the overall management of activities within the scope of the approved project plan. Please consult the HHS GPS Section II and 45 CFR § 75.308 for aspects of your funded project that will require prior approval from the Grants Management Officer for any changes. Modifications to your approved project that will require prior approval include, but are not limited to: a change in the scope or the objective(s) of the project or program (even if there is no associated budget revision, such as reduction in services, closing of service or program site(s)); significant budget revisions, including changes in the approved cost-sharing or matching; a change in a key person specified in your application; reduction in time devoted to the project by the approved project director or principal investigator, either as percentage of full-time equivalent of 25% or more or absence for 3 months or more; or the subawarding, transferring or contracting out of any work that was not described in the approved proposal.

Closeout of Award

Upon expiration of your project period, if we do not receive acceptable final performance, financial, and/or cash reports in a timely fashion within the closeout period, and we determine that closeout cannot be complete with your cooperation or that of the Principal Investigator/ Project Director, we may elect to complete a unilateral closeout. (See F.3 Reporting below for closeout reporting requirements.) As a result, we may determine that enforcement actions are necessary, including on another existing or future award, such as withholding support or a high-risk designation.

Lobbying Prohibitions

You shall not use any funds from an award made under this announcement for other than normal and recognized executive legislative relationships. You shall not use funds for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

You shall not use any funds from an award made under this announcement to pay the salary or expenses of any employee or subrecipient, or agent acting for you, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

The above prohibitions include any activity to advocate or promote any proposed, pending, or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

Non-Discrimination Requirements

Pursuant to Federal civil rights laws, if you receive an award under this announcement you must not discriminate on the basis of race, color, national origin, disability, age, and in some cases sex and religion. The HHS Office for Civil Rights provides guidance for complying with civil rights laws that prohibit discrimination. <https://www.hhs.gov/civil-rights/index.html>.

HHS provides guidance to recipients of federal financial assistance on meeting the legal obligation to take reasonable steps to provide meaningful access to persons with limited English proficiency. See *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, 68 Fed. Reg. 47311, 47313 (HHS Office for Civil Rights, 2003, www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf). You must ensure your contractors and subrecipients also comply with federal civil rights laws.

The *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care* (National CLAS Standards), 78 Fed. Reg. 58539, 58543 (HHS Office of Minority Health, 2013, www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23164.pdf), provides a practical framework for applicants to provide quality health care and services to culturally and linguistically diverse communities, including persons with limited English proficiency. Compliance with the National CLAS Standards meets the legal obligation to take reasonable steps to provide meaningful access to persons with limited English proficiency.

Smoke- and Tobacco-free Workplace

The HHS/OASH strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the

HHS/OASH mission to protect and advance the physical and mental health of the American people.

Acknowledgement of Funding and HHS Rights to Materials and Data

Each year's annual appropriation requires that when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all organizations receiving Federal funds, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state— (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

You must also acknowledge Federal support in any publication you develop using funds awarded under this program, with language such as:

This publication (journal article, etc.) was supported by Award No. _____ from the Office of the Assistant Secretary of Health (OASH). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of OASH.

All publications you develop or purchase with funds awarded under this announcement must be consistent with the requirements of the program. You own the copyright for materials that you develop under this award, and pursuant to 45 CFR § 75.322(b), HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for Federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal government has the right to obtain, reproduce, publish, or otherwise use data

produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

Trafficking in Persons

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104). For the full text of the award term, go to http://www.hhs.gov/opa/grants/trafficking_in_persons_award_condition.html. If you are unable to access this link, please contact the Grants Management Specialist identified in this funding opportunity announcement to obtain a copy of the term.

Efficient Spending

This award may also be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications available at <http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/>

Whistleblower Protection

If you receive an award, you will be subject to a term and condition that applies the terms of 48 CFR § 3.908 to the award, and requires that you inform your employees in writing of employee whistleblower rights and protections under 41 U.S.C. § 4712 in the predominant native language of the workforce.

Same-sex Spouses, Marriages, and Households

A standard term and condition of award will be included in the final Notice of Award (NOA) that states: “In any grant-related activity in which family, marital, or household considerations are, by statute or regulation, relevant for purposes of determining beneficiary eligibility or participation, grantees must treat same-sex spouses, marriages, and households on the same terms as opposite-sex spouses, marriages, and households, respectively. By “same-sex spouses,” HHS means individuals of the same sex who have entered into marriages that are valid in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By “same-sex marriages,” HHS means marriages between two individuals validly entered into in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By “marriage,” HHS does not mean registered domestic partnerships, civil unions, or similar formal relationships recognized under the law of the jurisdiction of celebration as something other than a marriage.”

Human Subjects Protection

Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in 45 CFR part 46. You may find it online at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

Applicants that plan to engage in research involving human subjects are encouraged to provide information regarding participation in research in their recruitment efforts and provide a link to www.hhs.gov/about-research-participation.

Research Integrity

An applicant for or recipient of PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with 42 C.F.R. part 93, including have written policies and procedures for addressing allegations of research misconduct that meet the requirements of part 93, file an Assurance of Compliance with the Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity consistent with 42 C.F.R. § 93.300. The assurance must state that the recipient (1) has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) complies with its own policies and procedures and the requirements of part 93. More information is available at ori.hhs.gov/assurance-program.

3. Reporting

Performance Reports

You must submit performance reports on a semi-annual basis. Your performance reports must address content required by 45 CFR § 75.342(b)(2). The awarding program office may provide additional guidance on the content of the progress report. You must submit your performance reports by the due date indicated in the terms and conditions of your award via upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

You will also be required to submit a final performance report covering the entire project period 90 days after the end of the project period. You must submit the final report by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

Performance Measures

At the end of each funding year of this initiative, you should be able to

- Describe collaboration with any partnering organizations and entities that have been specifically named as a subrecipient to carry out any aspect for this project.
- Describe any validation work that has been conducted for this project.
- Describe how your accomplishments and progress have contributed to your overall project goals.
- Identify the specific dissemination efforts of the initiative, e.g., manuscript, publications, conference presentations or other methods of disseminating results and outcomes.

Financial Reports

You will be required to submit quarterly Federal Financial Reports (FFR) (SF-425). Your specific reporting schedule will be issued as a condition of award. You will also be required to submit a final FFR covering the entire project period 90 days after the end of the project period. You must submit FFRs via our grants management system (GrantSolutions.gov) FFR module.

Quarterly cash reporting to the HHS Payment Management System on the FFR is also required. Please note, at this time, these FFR reports are separate submissions via the Payment Management System. At this time, data is not transferable between the two systems and you will report twice on certain data elements.

Audits

If your organization receives \$750,000 or greater in Federal funds, it must undergo an independent audit in accordance with 45 CFR part 75, subpart F.

Non-competing Continuation Applications and Awards

Each year of the approved project period, you will be required to submit a noncompeting application which includes a progress report for the current budget year, and work plan, budget and budget justification for the upcoming year. Specific guidance will be provided via Grant Solutions well in advance of the application due date. HHS/OASH will award continuation funding based on availability of funds, satisfactory progress of the project, grants management compliance, including timely reporting, and continued best interests of the government. Additionally, failure to provide final progress or financial reports on other awards from HHS may affect continuation funding.

FFATA and FSRS Reporting

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (<http://www.FSRS.gov>) for all sub-awards and sub-contracts issued for \$25,000 or more as well as addressing executive compensation for both recipient and sub-award organizations.

Reporting of Matters Relating to Recipient Integrity and Performance

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph A.2 of Appendix XII to 45 CFR part 75—Award Term and Condition for Recipient Integrity and Performance Matters. This is a statutory requirement (41 U.S.C. § 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. For more information about this reporting requirement related to recipient integrity and performance matters, see Appendix XII to 45 CFR part 75.

Other Required Notifications

Before you enter into a covered transaction at the primary tier, in accordance with 2 CFR § 180.335, you as the participant must notify HHS/OASH, if you know that you or any of the principals for that covered transaction:

- (a) Are presently excluded or disqualified;
- (b) Have been convicted within the preceding three years of any of the offenses listed in 2 CFR § 180.800(a) or had a civil judgment rendered against you for one of those offenses within that time period;
- (c) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in 2 CFR § 180.800(a); or
- (d) Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

At any time after you enter into a covered transaction, in accordance with 2 CFR § 180.350, you must give immediate written notice to HHS/OASH if you learn either that—

- (a) You failed to disclose information earlier, as required by 2 CFR § 180.335; or
- (b) Due to changed circumstances, you or any of the principals for the transaction now meet any of the criteria in 2 CFR § 180.335.

G. CONTACTS

Administrative and Budgetary Requirements:

For information related to administrative and budgetary requirements, contact the HHS/OASH grants management specialist listed below.

Jessica Shields

Office of Grants Management

1101 Wootton Parkway, Suite 550

Rockville, MD

Phone: 240-453-8822

Email: Jessica.shields@hhs.gov

Program Requirements

For information on program requirements, please contact the program office representative listed below.

Ana Carolina Loyola Briceno

Health Scientist

Office of Population Affairs

Phone: 240-276-8309

Email: AnaCarolina.LoyolaBriceno@hhs.gov

Electronic Submission Requirements

For information or assistance on submitting your application electronically via Grants.gov, please contact Grants.gov directly. Assistance is available 24 hours a day, 7 days per week.

GRANTS.GOV Applicant Support

Website: www.grants.gov

Phone: 1-800-518-4726

Email: support@grants.gov

H. OTHER INFORMATION

Awards under this Announcement

We are not obligated to make any Federal award as a result of this announcement. If awards are made, they may be issued for project periods shorter than indicated. Only the grants officer can bind the Federal government to the expenditure of funds. If you receive communications to negotiate an award or request additional or clarifying information, this does not mean you will receive an award; it only means that your application is still under consideration.

Application Elements

The below is a summary listing of all the application elements required for this funding opportunity.

Application for Federal Assistance (SF-424)

Budget Information for Non-construction Programs (SF-424A)

Assurances for Non-construction Programs (SF-424B)

Disclosure of Lobbying Activities (SF-LLL)

Project Abstract Summary

Project Narrative – Submit all Project Narrative content as a single acceptable file, specified above.

Budget Narrative – Submit all Budget Narrative content as a single acceptable file, specified above.

Appendices – Submit all appendix content as a single acceptable file, specified above **in the Attachments section of your Grants.gov application.**

Appendices should include:

- References for project and/or budget narratives
- Project work plan:
 - Organized by overarching goals of project with objectives for each goal clearly listed
 - Each goal and objective should be accompanied by anticipated start and completion dates
 - Each objective should include measures of accomplishment and list tasks in support of those accomplishments
 - For each objective, persons responsible for accomplishing tasks should be identified
- Letters of commitment from subrecipient organizations, if applicable
- Curricula vitae and/or résumés for Key Project Personnel
- Organizational chart
- Any other key information or documents required to review project proposal

Diane Foley

Diane Foley MD, FAAP
Deputy Assistant Secretary of Population Affairs

April, 12, 2019

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